Subject Name: _____ **Date** _____

Title of Study: H02-131 Telemedicine Intervention to Improve Depression in Care in Rural CBOCs

Principal Investigator: Dean Robinson, M.D. **VAMC:** Shreveport, LA

Definition of Consent Form

This consent form gives detailed information about the research study that you will be able to discuss with your doctor. It is not meant to frighten or alarm you; it is an effort to make you better informed in order for you to make a decision as to whether or not you wish to participate. This process is known as "informed consent."

Why is This Study Being Done?

You are invited to participate in a research study. The purpose of this research is to study how we can use telemedicine to improve treatment for people with depression who live a long distance from a VA Medical Center. By telemedicine, we mean using a telephone and an interactive video (a video camera connected to a TV) to improve your access to quality care. You were selected as a possible participant in this study because you currently have an appointment at a VA Community Based Outpatient Clinic (CBOC) and you have symptoms of depression.

The study will compare the quality and outcomes of depression treatment in VA CBOCs including Mountain Home, AR; El Dorado, AR; Hot Springs, AR; Monroe, LA; Longview, TX; Hattiesburg, MS; and Meridian, MS. Three of the CBOCs will be randomly assigned (like the toss of a coin) to receive the following: patients participating in the study will receive educational materials about depression, and occasional telephone calls from a nurse (and perhaps a clinical pharmacist) who will ask questions about depression symptoms, discuss the effects of any antidepressant medications that might have been prescribed, and make treatment recommendations to the study participant's regular primary care doctor. The purpose of this research study is to determine whether these extra efforts improve depression symptoms and patient satisfaction.

How Many People Will Take Part in the Study?

Approximately 598 primary care patients who are feeling depressed will be enrolled in the study from Arkansas, Louisiana, Mississippi and Texas.

SUBJECTS IDENTIFICATION *(I.D. plate or give name-late, first, middle)*	
- -	_____ Signature of Subject

Subject Name: _____ **Date** _____

Title of Study: H02-131 Telemedicine Intervention to Improve Depression in Care in Rural CBOCs

Principal Investigator: Dean Robinson, M.D. **VAMC:** Shreveport, LA

What Is Involved in the Study?

If you agree to be a part of this study, the following will happen.

1. All study participants will be asked to complete three research interviews over the phone. Your first research interview will consist of a one-hour interview to determine your overall health status and the severity of your depression. Follow-up one-hour phone interview will take place 6 and 12 months later. You will be compensated for your time. You will receive $40 for the first one-hour interview, $40 for the second one-hour interview and $40 for the third one-hour interview.
2. For all study participants, your regular primary care doctor may recommend a referral for a face-to-face appointment to see a psychiatrist at the VA Medical Center or recommend an interactive video consult with a psychiatrist. You may choose either of the two options or neither option. If you choose the interactive video consult, you will go to the CBOC and talk to a psychiatrist who is at the nearest VA Medical Center using a video camera connected to a TV. The psychiatrist may then make treatment recommendations to your primary care doctor.
3. For all study participants, the research team will review your medical records to see what services and treatments you are receiving currently and what other treatments you may receive over the next year.

How Long Will I Be in the Study?

The study will continue for up to one year. During this study, you and your regular primary care doctor ll be in charge of your treatment.

What Are the Risks of the Study

Your participation in the protocol involves the following risk: inconvenience of time.

Otherwise, there are no expected risks or costs to you as a participant in this study. You will be told of y new risks.

Are There Benefits to Taking Part in the Study?

If you agree to take part in this study, there may or may not be direct medical benefit to you. We nnot, and do not, guarantee that you will receive any benefits from this study. We hope information learned om this study will benefit other patients with depression in the future.

What Other Options Are There?

Participating in this study will not prevent you from receiving your usual medical care from your gular primary care doctor. An alternative is not to participate.

Subject's Initials _____

Subject Name: _____ Date _____

Title of Study: H02-131 Telemedicine Intervention to Improve Depression in Care in Rural CBOCs

Principal Investigator: Dean Robinson, M.D. VAMC: Shreveport, LA

What About Confidentiality?

All information obtained during this study will remain confidential. Study records may only be seen by study investigators, at both Shreveport and Little Rock, and the Institutional Review Boards at the Louisiana State University Health Sciences Center (LSUHSC) in Shreveport and the VA Medical Center in Shreveport. Any information obtained during this study and identified with you as a subject will remain confidential and will be disclosed only with your permission. Your information, in all cases, will be treated as confidential except as otherwise prohibited by federal or state law. The results of this research may be used or reported in a scientific presentation or publication, but you will not be personally identified and your confidentiality will be maintained.

By signing this form, you are giving permission for us to make records available to study investigators at both Shreveport and Little Rock, and the LSUHSC's Institutional Review Board for the Protection of Human Research Subjects and the VA Research and Development Committee, all of who must maintain confidentiality.

What Are the Costs?

As stated above, you will be compensated for your time. You will receive $40 for the first one-hour interview, $40 for the second one-hour interview and $40 for the third one-hour interview. You will not incur any expenses related to participating in this study. If you normally have to pay co-payments when you receive care at the VA, you may be asked to make a co-payment at your visits including visits for interactive video consults.

What Are My Rights as a Participant?

Participation in research is entirely voluntary. You may refuse to participate or withdraw at any time without jeopardy to the medical care you will receive at this institution, without prejudice to your future relationship with this institution or loss of benefits to which you are entitled. Signing this form does not mean that you lose any legal rights to which you are entitled.

In case of adverse (bad) effects or physical injury resulting from this study, eligible veterans are entitled to medical care and treatment. Compensation may or may not be payable in the event of physical injury arising from this study under applicable federal law. Further information about compensation and medical treatment may be obtained from the medical administration service at this VA Medical Center.

Whom Do I Call if I Have Questions or Problems?

If you have any questions, please ask us. If you have any additional questions later, Dr. Dean Robinson at (318) 221-8411, ext. 6417, will be happy to answer them.

Subject's Initials _____

Subject Name: _____ **Date** _____

Title of Study: H02-131 Telemedicine Intervention to Improve Depression in Care in Rural CBOCs

Principal Investigator: Dean Robinson, M.D. **VAMC:** Shreveport, LA

Whom Do I Call if I Have Questions or Problems?

If you have questions about your rights as a research participant, you may contact the Chairperson of LSUHSC's Institutional Review Board at (318) 675-5409 or the Chief of Staff, Overton Brooks VA Medical Center at (318) 424-6089. We will let you and your physician know of any important discoveries made during this study, which may affect you, your condition, or your willingness to participate in this study.

I have read the above statement and have been able to ask questions and express concerns, which have been satisfactorily responded by the investigator. I understand the purpose of the study as well as the potential benefits and risks that are involved. I hereby give my informed and free consent to be a participant in the study. I have been given a copy of this consent form.

_____ _____ _____ AM / PM

Subject's Signature *(Surrogate Consent will not be used).* Date Time

_____ _____

Signature of Witness Witness (print)

_____ _____

Signature of Investigator Date

REVISED

IRB Approval Period: Start Date: 10/18/03 to End Date: 10/17/04 APPROVED